Specialty Independent Review Organization

Notice of Independent Review Decision

Date notice sent to all parties: 8/19/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
The item in dispute is the prospective medical necessity of L3-4 decompression L4-5 explore fusion, hardware removal; 1 day LOS.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of L3-4 decompression L4-5 explore fusion, hardware removal; 1 day LOS.

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient was injured while walking backward rolling a heavy tire wheel. He tripped on a metal bar and fell with the tire falling onto him. Persistent back and leg pain were noted along with leg weakness. The xxxx dated summary revealed that the patient had symptomatic hardware post anterior lumbar fusion at L4-5 on 4 16 14. This was after a 6/19/13 dated decompression at L4-5 and L5-S1. At L3-4 the patient was noted to have a positive response to a transforaminal injection indicating stenosis at that level. Serial MRIs including from xxxx were noted to show decreased CSF at the nerve roots at L3-4 per the Attending Physician. The radiologist noted a prior fusion and facet arthritis at L4-5. A disc bulge, borderline spinal stenosis and mild bilateral neural foraminal narrowing was noted at L3-4. At L5-S1, there was noted facet arthritis, neural foraminal narrowing and prior laminectomy. The provider indicated that his patient had an indication for

hardware removal and prior fusion exploration along with decompression at the L3-4 level. Prior records revealed documentation of diagnoses including lumbar radicular syndrome, low back pain and post laminectomy syndrome. Exam findings included grade 4/5 on the right side at the tibialis anterior and EHL. There was tenderness directly over the pedicle screws. There was a positive psychosocial clearance dated xxxx. Recent treatments were noted to include multiple medications. A xxxx dated Attending Physician note related the lack of hardware subsidence and “fusion visible within the disc space.” xxxx dated physical therapy records were noted. Denials related the lack of hardware block and/or evidence of neural compression at L3-4.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The clinical back pain and leg weakness have not been reasonably documented to correlate with the MRI findings. The clinical and radiographic findings have multiple plausible sources and specific pain generators have not been fully documented and/or rolled out. A hardware block with positive response has not been documented. Recent and comprehensive/less invasive, detailed non-operative treatments have not been documented to have been tried and failed. Therefore, applicable guidelines referenced below do not support the requests at this time. The request is not medically necessary.

ODG Low Back Chapter - Spinal Fusion: Patient Selection Criteria for Lumbar Spinal Fusion:

(A) Recommended as an option for the following conditions with ongoing symptoms, corroborating physical findings and imaging, and after failure of non-operative treatment (unless contraindicated e.g. acute traumatic unstable fracture, dislocation, spinal cord injury) subject to criteria below:

(1) Spondylolisthesis (isthmic or degenerative) with at least one of these:
  (a) instability, and/or
  (b) symptomatic radiculopathy, and/or
  (c) symptomatic spinal stenosis;

(2) Disc herniation with symptomatic radiculopathy undergoing a third decompression at the same level;

(3) Revision of pseudoarthrosis (single revision attempt);

(4) Unstable fracture;

(5) Dislocation;

(6) Acute spinal cord injury (SCI) with post-traumatic instability;

(7) Spinal infections with resultant instability;

(8) Scoliosis with progressive pain, cardiopulmonary or neurologic symptoms, and structural deformity;

(9) Scheuermann's kyphosis;

(10) Tumors.

(B) Not recommended in workers' compensation patients for the following conditions:

(1) Degenerative disc disease (DDD);
(2) Disc herniation;
(3) Spinal stenosis without degenerative spondylolisthesis or instability;
(4) Nonspecific low back pain.

(C) Instability criteria: Segmental Instability (objectively demonstrable) - Excessive motion, as in isthmic or degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 15 degrees L1-2 through L3-4, 20 degrees L4-5, 25 degrees L5-S1. Spinal instability criteria includes lumbar inter-segmental translational movement of more than 4.5 mm. (Andersson, 2000) (Luers, 2007) (Rondinelli, 2008)

(D) After failure of two discectomies on the same disc [(A)(2) above], fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

(E) Revision Surgery for failed previous fusion at the same disc level [(A)(3) above] if there are ongoing symptoms and functional limitations that have not responded to non-operative care; there is imaging confirmation of pseudoarthrosis and/or hardware breakage/malposition; and significant functional gains are reasonably expected. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. Workers compensation and opioid use may be associated with failure to achieve minimum clinically important difference after revision for pseudoarthrosis (Djurasovic, 2011) There is low probability of significant clinical improvement from a second revision at the same fusion level(s), and therefore multiple revision surgeries at the same level(s) are not supported.

(F) Pre- operative clinical surgical indications for spinal fusion should include all of the following:

(1) All physical medicine and manual therapy interventions are completed with documentation of reasonable patient participation with rehabilitation efforts including skilled therapy visits, and performance of home exercise program during and after formal therapy. Physical medicine and manual therapy interventions should include cognitive behavioral advice (e.g. ordinary activities are not harmful to the back, patients should remain active, etc.);

(2) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or MRI demonstrating nerve root impingement correlated with symptoms and exam findings;

(3) Spine fusion to be performed at one or two levels;

(4) Psychosocial screen with confounding issues addressed; the evaluating mental health professional should document the presence and/or absence of identified psychological barriers that are known to preclude post-operative recovery;

(5) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing; (Colorado, 2001) (BlueCross BlueShield, 2002)

(6) There should be documentation that the surgeon has discussed potential alternatives, benefits and risks of fusion with the patient;

(7) For average hospital LOS after criteria are met, see Hospital length of stay (LOS)

Hardware Injection/Block: Recommended only for diagnostic evaluation of failed back surgery syndrome. This injection procedure is performed on patients who have undergone a fusion with hardware to determine if continued pain is caused by the hardware. If the steroid/anesthetic medication can eliminate the pain by reducing the swelling and inflammation near the hardware, the surgeon may decide to remove the patient's hardware. (Guyer, 2006)

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**